

**UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**In the Matter of**

**ECUMED HEALTH GROUP**

**FDA Docket: 2004H-0322**

**a corporation,**

**and**

**AMADOR REYES,  
JUAN C. CARRAI,  
RICHARD W. STONE, M.D., and  
ERLINDA E. ENRIQUEZ, M.D.,**

**individuals.**

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**DEFENDANT JUAN C. CARRAI'S INTERROGATORIES TO COMPLAINANT**

Defendant, Juan Carlos Carrai ("Carrai"), by and through its undersigned counsel, hereby propounds Interrogatories upon the Center for Devices and Radiological Health, Food and Drug Administration, United States Department of Health and Human Services' (the "Complainant"), to be answered within thirty (30) days.

**I. DEFINITIONS**

1. "Complainant" shall mean the Center for Devices and Radiological Health, Food and Drug Administration, United States Department of Health and Human Services', and its respective representatives, agents, employees, attorneys and accountants.
2. "Ecumed" shall mean the Respondent, Ecumed Health Group, Inc.
3. "Carrai" shall mean Respondent, Juan C. Carrai.

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4. "Reyes" shall mean Respondent, Amador Reyes.
5. "Dr. Stone" shall mean Respondent, Richard W. Stone, M.D.
6. "Dr. Enriquez" shall mean Respondent, Erlinda E. Enriquez, M.D.
7. "Respondents" shall mean Ecumed, Carrai, Reyes, Dr. Stone and Dr. Enriquez, collectively.
8. "Complaint" shall mean the Complaint filed by the Complainant against Respondents on July 19, 2004.
9. "Answer" shall mean the Answer and Affirmative Defenses of Juan C. Carrai, filed on September 16, 2004.
10. "MQSA" shall mean the Mammography Quality Standards Act of 1992, as set forth in the Complaint.
11. "ACR" shall mean the American College of Radiology.
12. "Certificate" shall mean the MQSA certificate, as required by 21 C.F.R. § 900.11 (a), (b) (1) (ii).
13. "Penalty" shall mean the civil money penalties assessed under 42 U.S.C. § 263b (h) (3) (A) and 42 U.S.C. § 263b (h) (3) (D).
14. "And" and "or" as used herein are terms of inclusion and not of exclusion, and shall be construed either disjunctively or conjunctively as necessary to bring within the scope of each request any document and/or electronic data that might otherwise be construed to be outside its scope.
15. "Relating to," "evidencing" or "reflecting" means to make a statement about, refer to, discuss, describe, evidence, reflect, show, support, contain, comprise, identify, or in any way to

pertain to, in whole or in part, or otherwise to be used, considered, or reviewed in any way in connection with, the specified subject. Documents and/or electronic data that "relate to" a subject also include those which were specifically rejected and those which were not relied or acted upon.

16. "Communication" means the oral and written utterance, notation or statement of any nature whatsoever, by and to whomever made, including, without limitation, agreements and other understanding between or among two or more people, consultations, conversations, correspondence, dialogues, discussion, interviews, meetings, telegrams and telephone calls. This definition includes all communications for which you claim a privilege.

17. "Describing" means any document and/or electronic data that, in whole or in part, describes, characterizes, delineates, explicates, deliberates, evaluates, appraises, assesses or provides a general explanation of the specified subject.

18. "Document" or "documents" as used herein shall mean the original and any copy, regardless of its origin and location, of all writings of any kind whatsoever including, but not limited to, all abstracts, accounting journals, accounting ledgers, advertisements, affidavits, agendas, agreements or proposed agreements, analyses, appointment books, appraisals, articles of incorporation, balance sheets, bank checks, bank deposit or withdrawal slips, bank credit or debit memoranda, bank statements, blueprints, books, books of account, budgets, bulletins, bylaws, canceled checks, charts, checks, codes, communications, communications with government bodies, computer data or printouts, conferences, contracts, correspondence, data processing cards, data sheets, desk calendars, details, diagrams, diaries, disks or data compilations from which information can be obtained or translated, drafts, drawings, electromagnetic tapes, files, films, financial calculations, financial projections, financial statements, graphs, handwritten notes or comments however

produced or reproduced, indexes, insertions, instructions, internal accounting records, interoffice communications, invoices, ledgers, letters, lists, logbooks, manuals, memoranda, microfilm, minutes of meetings, motion pictures, newspaper or magazine articles, networks, nonconforming copies which contain deletions, notations or records of meetings, notes, notices of wire transfer of funds, outlines, pamphlets, papers, passbooks, periodicals, photocopies, photographs, pictures, plans, preliminary drafts, press releases, proposals, publications, punch cards, raw and refined data, receipts, recommendations, records, records of conferences or conversations or meetings, records of payment, reports, resolutions, results of investigations, schedules, schematics, sepias, shipping papers, slides, specifications, speeches, statements of account, studies, summaries, surveys, tape recordings, tax returns, telegrams, telephone logs and records, telephone and other conversations or communications, teletypes, telexes, transcripts, transcripts of tape recordings, video tapes, voice records, vouchers, work papers, worksheets, written notations, and any and all other papers similar to any of the foregoing. Any document containing thereon or attached thereto any alterations, comments, notes or other material not included in the copies or originals or referred to in the preceding definition shall be deemed a separate document within said definition. Any document shall include all exhibits, schedules or other writings affected by or referenced in any such document or other writings necessary to complete the information contained therein or make it not misleading.

19. "Person" means any natural person, corporation, partnership, company, sole proprietorship, association, institute, joint venture, firm, governmental body, or other legal entity, whether privately or publicly owned or controlled, for profit or not-for-profit, or partially or fully government owned or controlled.

20. "Any" means one or more.

21. "Year" means calendar year.

22. The singular form of a noun or pronoun shall be considered to include within its meaning the plural form of the noun or pronoun, and vice versa. The masculine form of a noun or pronoun shall be considered to include within its meaning the feminine form of the noun or pronoun, and vice versa.

23. Regardless of the tense employed, all verbs shall be read as applying to the past, present and future as is necessary to make any paragraph more, rather than less, inclusive.

## **II. INSTRUCTIONS**

For purposes of responding to these interrogatories, the following instructions shall apply:

1. In each of your answers to these interrogatories, you are requested to provide not only such information as is in your possession, but also all information as is reasonably available, whether or not it is in your possession. In the event you are able to provide only part of the information called for by any particular interrogatory, provide all of the information you are able to provide and state the reason for your inability to state the remainder.

2. Every interrogatory herein shall be deemed a continuing interrogatory. You are to supplement your answers promptly if and when you obtain relevant information, in addition to or in any way inconsistent with your initial answer to any such interrogatory.

3. If you object to, or otherwise decline to answer, any portion of any interrogatory, please provide all information called for in that portion of the interrogatory to which you do not object or to which you do not decline to answer. If you object to an interrogatory on the ground that it is too broad (*i.e.*, that it calls both for information which is relevant to the subject matter of the action and for information which is not relevant), please provide such information as you concede to be relevant. If you object to an interrogatory on the ground that it would constitute an undue burden to provide an answer, please provide such requested information as can be supplied without undertaking such undue burden. For those portions of any interrogatory to which you object or otherwise decline to answer, state the reason for such objection or declination.

4. Each interrogatory shall be answered separately, fully and completely without reference to any answer of any other interrogatory.

5. The relevant period of time for these interrogatories is from January 1, 2002 to the present.

### **III. INTERROGATORIES**

1. Please state the name, address and telephone number of the person and/or persons answering these interrogatories and, if applicable, the person's official position or relationship with the party to whom the interrogatories are directed.

2. Please state in detail, and not merely summary fashion, the reason why the Complainant addressed the September 14, 2001 and January 4, 2002, letters to Dr. Stone, and not Carrai.

3. Please state the name and telephone numbers of the person(s) with whom the ACR discussed testing information, as alleged in ¶ 25 of the Complaint, and describe in detail and not in summary fashion, the nature of the conversation.

4. Please provide the dates of issuance of any and all Certificates issued by the FDA to Ecumed including, but not limited to, any and all interim notices and/or provisional Certificates; and the manner in which said Certificates were provided to Ecumed..

5. Please state in detail, and not merely summary fashion, all facts that support your contention that Carrai was involved in, knew or should have known that Ecumed could not lawfully conduct mammography examinations upon the expiration of the MQSA Certificate, as alleged in ¶ 19 of the Complaint; and/or that Carrai was aware of, and understood, the administrative procedure required by the MQSA.

6. Please state in detail, and not merely summary fashion, all facts that support your contention that Carrai was advised on December 21, 2001, that Ecumed's mammography unit failed to comply with the ACR's standards for clinical quality imaging, as alleged in ¶ 22 of the Complaint.

7. Please state in detail, and not merely summary fashion, all facts that support your contention that Carrai conducted mammography examinations between December 9, 2001 and May 5, 2003.

8. Please state in detail, and not merely summary fashion, all facts that support your contention that penalties in the sum of \$1,211,000.00 should be imposed against Carrai.

9. Please state the name, address and telephone numbers of all persons believed or known by you to have any knowledge concerning any of the facts, issues and/or allegations raised in the Complaint, without limitation, and describe in detail and not in summary fashion each such person's knowledge, and include any and all witnesses who will testify at trial with a brief description of their proposed testimony.

**Names, Addresses and  
Telephone Numbers**

**Description of Persons' Knowledge in Detail**

10. Please identify any and all communications between Complainant and Respondent regarding any and all issues alleged in the Complaint including, without limitation, telephone calls, faxes, e-mails, correspondence, and for each such communication, please state the nature and substance of the communication and the names, addresses and telephone numbers of all persons with knowledge of same.

11. Please identify any and all communications including telephone calls, faxes, e-mails, and correspondence, between Complainants and any third parties regarding the Penalties or alleged violations as set forth in the Complaint, and for each such communication, please state the nature and substance of the communication and the names, addresses and telephone numbers of all persons with knowledge of same.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing was sent via facsimile and U.S. Mail on this 5<sup>th</sup> day of February, 2005 to:

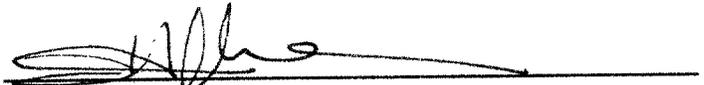
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Respectfully submitted,



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